

REMARKS

Claims 2-7, 10 and 11 are in this application. Claims 8 and 9 have been cancelled and Claim 10 has been amended. Claim 10 has been amended to delete the phrase "or preventing", a comma has been inserted after vanadium (V) and the word "orally" was added after the phrase "are administered." This is supported in the specification including at page 3, line 8 and page 5, lines 1-4 and the Example on page 5, where patients were given the composition orally in the form of food supplementation. New claim 11 has been added and it is directed to a method for preventing an outbreak of psoriasis

Based on the amendments described above, the objections to claims 8-10 are moot.

According to the action, claims 2-7 and 10 are rejected under 35 USC 112, first paragraph because while according to the Examiner, the claims are enabled for treating psoriasis, the claims are not enabled for preventing psoriasis. This is respectfully traversed.

The phrase "or preventing" psoriasis has been deleted from claim 10 and new claim 11 has been added. There is support for new claim 11 on page 3, lines 2-5 of the specification where it is stated that "close family members of these cancer patients, who otherwise were healthy but who also had suffered from bouts of psoriasis, the same natural dietary components ingested could cause a favorable clinical effect." This passage implies that an outbreak of psoriasis was prevented in this population that had a history of psoriasis but did not necessarily have psoriasis at the time of administration of the components of this invention. In addition, according to the description bridging pages 5 and 6 of the specification, the continuous administration of the composition in some patients prevented recurrence of psoriasis. Therefore, it is respectfully requested that this rejection be withdrawn and claim 11 be allowed.

According to the action, claim 5 is rejected under 35 USC 112, first paragraph as failing to comply with the written description requirement. This is respectfully traversed.

The phrase "neurogenic lipids" is a term that is understood by a person skilled in the art. Neurogenic is described in the medical context as starting with or having to do with the nerves or the nervous system. Lipids are a well defined class of molecules usually isolated from cells and tissues by extraction with nonpolar solvents. Neurogenic lipids are lipids that have been extracted from the nervous system. The terms neurogenic and lipids are given their normal meaning and a person skilled in the art would understand the meaning of the term.

Therefore, it is respectfully requested that this rejection be withdrawn.

According to the action, claims 2-10 are rejected under 35 USC 112, second paragraph as being indefinite. This is respectfully traversed.

Claim 10 has been amended to delete the word "optionally." Therefore, it is respectfully requested that this rejection be withdrawn.

According to the action, claims 8 and 9 are rejected under 35 USC 112 and 35 USC 102(b). . These claims have been deleted and thus, the rejections are moot.

According to the action, claims 2 to 7 and 10 are rejected as unpatentable under 35 USC 103(a) over Tallberg et al. (Studies on Mitochondrial Regulation of the Genome) in view of Bodaness (U.S. Patent 5,563,132) and Dong et al. (CN 1372926). This is respectfully traversed.

Tallberg et al. teaches a composition comprising amino acids (such as (serine and isoleucine), trace elements (such as chromium, selenium, tin, vanadium and wolfram) and folic acid. This composition is used as a bio-immunotherapy for patients suffering from various kinds of cancers including cancers of the skin. Tallberg et al. does not teach the use of the composition in the treatment of psoriasis.

Bodaness teaches the use of a composition comprising metal ion complexes for the treatment of skin cancers, premalignant lesions, psoriasis and other skin conditions. In fact, Bodaness teaches the use of a peroxide-reactive metal-ion containing molecule in connection with a peroxide compound. These two components together are able to destroy tissue at a specific locus in the treatment of cancers. In addition, Bodaness teaches that the same components can be incorporated in creams, lotions and ointments etc, which are used for topical treatment of e.g. psoriatic skin. Bodaness does not mention the presence of amino acids in the composition, nor oral administration.

Dong et al. describes the use of zinc for the treatment of skin in various diseases such as skin cancer and psoriasis and does not disclose or suggest oral administration.

The Examiner states that it is obvious for a person skilled in the art to utilize compositions useful for skin cancers also on psoriasis patients. Applicants respectfully disagree. The pathology of psoriasis is very different from that of cancer. Psoriasis is hyperproliferation of epidermal keratinocytes combined with inflammation of the epidermis and dermis. There are no tumors, malignant growth or uncontrolled cell division associated with psoriasis. Therefore, psoriasis and cancer are two very different types of diseases and it cannot be considered obvious that a treatment useful for cancer is also useful for psoriasis.

Claim 10 has been amended to recite that the components are administered orally. Tallberg discloses a method of treating cancer and as the Examiner noted does not teach the use of compositions for treatment of psoriasis or expressly recite the incorporation of zinc. There is no combination of the references that leads to the claimed invention and in fact, the Examiner is relying on impermissible hindsight.

According to MPEP 2141 when applying 35 USC 103, the following tenets of patent law must be adhered to:

(A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention and (D) reasonable expectation of success is the standard with which obviousness is determined.

In making this rejection, the Examiner is relying on impermissible hindsight.

A reference must be considered for what it would teach someone skilled in the art at the time the invention was made and not be applied based on "hindsight". See *Panduit Corp. V. Dennison Manufacturing Co.* 227 USPQ 337, 343 (Fed. Cir. 1985):

It is impermissible to first ascertain factually what applicants did and then view the prior art in such a manner as to select from the random facts of that art only those which may be modified and then utilized to reconstruct appellants' invention from such prior art.

In making its obviousness determination, a court must view the prior art without reading into that art the patent's teachings. *Vandenberg v. Dairy Equipment*, 224 U.S.P.Q. 195 (Fed. Cir. 1987) citing *In re Sponnoble*, 160 U.S.P.Q. 237 (CCPA 1969). In *Uniroyal . Rudkin-Wiley*, 50 U.S.P.Q.2d 1434, 1438 (Fed. Cir. 1988) the CAFC stated:

The obviousness standard, while easy to expound, is sometimes difficult to apply. It requires the decision maker to return to the time the invention was made. The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time...That which may be clear and thus obvious to a court, with the invention fully diagramed and aided by experts in the field, may have been a breakthrough of substantial dimension when first unveiled [citations omitted]. In this case we are convinced that the district court misapplied the obviousness standard. It has impermissibly used hindsight to reconstruct the claimed invention from prior art with the invention before it and aided by Uniroyal's expert, rather than viewing the invention from the position of a person of ordinary skill at the time it was made. When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.

Tallberg is focused on the treatment of cancer and one skilled in the art would not combine this reference with Dong that discloses the use of a totally different composition. While Bodaness discloses a complex of metal ions there is no teaching, suggestion or motivation that any of amino acids or elements disclosed in Tallberg can be used to treat psoriasis. There is no suggestion, teaching or motivation to combine the metal ions of Bodaness and zinc of Dong with Tallberg to develop a treatment for psoriasis and no combination of the references that leads to oral administration of the combination.

According to the U.S. Supreme Court in KSR v Teleflex and as included in the Examination Guidelines for Determining Obviousness Under 35 USC 103 “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” Since this has not been shown, it is respectfully requested that the rejection be withdrawn.

It is submitted that the present application is in condition for allowance and favorable consideration is respectfully submitted.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Janet I. Cord', is written over a horizontal line.

JANET I. CORD
LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NY 10023
REG. NO.: 33778 (212) 708-1935